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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,753	05/10/2002	Rick L. Pruter	02P1566	1568
24234	7590	02/13/2004	EXAMINER	
SIMMONS, PERRINE, ALBRIGHT & ELLWOOD, P.L.C. THIRD FLOOR TOWER PLACE 22 SOUTH LINN STREET IOWA CITY, IA 52240			JAIN, RUBY	
			ART UNIT	PAPER NUMBER
			3737	2

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/063,753

Applicant(s)

PRUTER, RICK L.

Examiner

Ruby Jain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 / 8/7/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Claim 19 objected to because of the following informalities: the preamble to the claim is too broad and vague and does not encompass the claimed invention. As possible revision might be -- An improved needle guiding apparatus for use with a medical imaging transceiver assembly, the needle guiding apparatus comprising: --. Appropriate correction is required.

Claim Rejections - 35 USC § 102

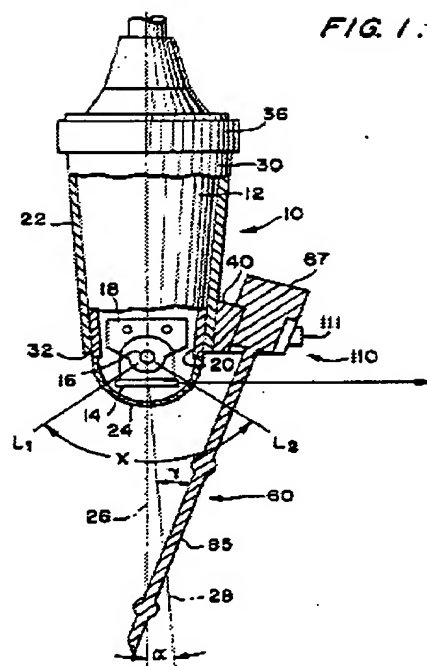
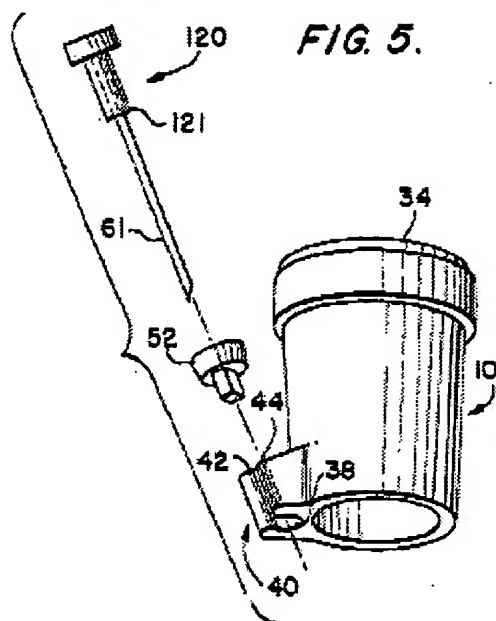
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 11-14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnea et al. U.S. Patent No. 4,567,896.

Regarding claims 1, 3, 4, 11-14, 18, Barnea discloses a method and apparatus comprising a sheath (10) having an opening at a top end for receiving a medical imaging transceiver (said sheath not having medical transceiver disposed therein), matter (40) attached to an exterior portion of the sheath, configured to assist in guiding a needle. The needle guide further has a mating structure thereon configured for coupling with a mounting bracket structure on the medical imaging transceiver (Figures 1 and 5).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnea as applied to claim 1 above, and further in view of Law et al. U.S Patent No. 5,469,853.

Regarding claim 2, Barnea discloses a sheath (10) having an opening at a top end for receiving a medical imaging transceiver (said sheath not having medical transceiver disposed therein), member (40) attached to an exterior portion of the sheath, configured to assist in guiding a needle (Figure 5). Barnea does not disclose wherein there is an adhesive on an interior surface of the sheath.

Law discloses wherein there is an adhesive on an interior surface of the sheath (column 33, lines 25-48).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was to provide an adhesive on an interior surface of the sheath, as per the teachings of Law into the teachings of Barnea, because the adhesive ensures that the object placed inside the sheath will remain at a fixed position, without moving, when the apparatus is moved. This would be necessary when a needle guide

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apparatus is placed into a patient. If the transceiver assembly were to move around inside the sheath, this may possibly affect the imaging of the tissue and lead to misdiagnosis of a disease.

4. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnea in view of Law as applied to claim 2 above, and further in view of Marmar U.S. Patent No. 4,865,590.

Regarding claims 5 and 8-10, Barnea discloses a sheath (10) having an opening at a top end for receiving a medical imaging transceiver (said sheath not having medical transceiver disposed therein), member (40) attached to an exterior portion of the sheath, configured to assist in guiding a needle (Figure 5). Law discloses wherein there is an adhesive on an interior surface of the sheath (column 33, lines 25-48). Barnea in view of Law does not disclose wherein there is a temporary adhesive cover disposed over the adhesive. Furthermore, Barnea in view of Law does not disclose wherein an ultrasonic weld, adhesive, or tape is disposed between and bonding the adapter and the sheath.

Marmar discloses wherein there is a temporary adhesive cover disposed over the adhesive. Furthermore, Marmar discloses wherein the needle guide, after having the cover removed, is adhesively mounted so that the lower plane of the gloved finger is in contact with the adhesive coated surface of the support (column 3, lines 50-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was to provide a temporary adhesive cover disposed over the

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adhesive, as per the teachings of Marmar into the teachings of Barnea in view of Law, because an adhesive cover is essential to protect against dirt and germs from adhering to the adhesive and possibly drying out the adhesive prior to use. The cover is designed to temporarily protect the adhesive.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was to disclose wherein an ultrasonic weld, adhesive, or tape is disposed between and bonding the adapter and the sheath, as per the teachings of Marmar into the teachings of Barnea in view of Law, because the means of attaching the needle guide to the sheath are versatile. As long as the needle guide is firmly held in place to the sheath, any disclosed method for attaching the needle guide to the sheath, i.e. using screws, ultrasonic welding, adhesives, or tape, are analogous.

Regarding claim 6, Barnea discloses an adapter configured for cooperation with a needle guide (40) (Figure 1).

Regarding claim 7, Barnea discloses a needle guide coupled to the sheath (Figure 5).

Allowable Subject Matter

5. Claims 16, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 19 and 20 are allowed. None of the prior art alone or in combination discloses a needle guiding apparatus comprising an elongated pull disposed inside a sterile sheath and attached to a cover, configured to facilitate removal of the cover from the adhesive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruby Jain whose telephone number is (703) 605-4250. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RJ

February 5, 2004


DENNIS W. RUHL
SUPERVISORY PATENT EXAMINER